DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

94819d

June 28, 2004

Ref: 04-DAL-WL-21

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

SmartBodyz Nutrition
1051 West Seventh, Suite 325
Fort Worth, TX 76102

Dear Sir or Madam:

This letter is in reference to your firm's marketing and distribution of ASN Canthaxanthin capsules and Bronze EZ Canthaxanthin capsules. The Food and Drug Administration (FDA) has reviewed your web site at the following address: www.dietsexercise.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of these products. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. Furthermore, articles other than food that are intended to affect the structure or any function of the body of man are drugs [Section 201(g)(1)(C) of the Act]. Your web site claims that your canthaxanthin products are useful in the prevention of sun damage, genetic damage, and skin cancer. The labeling of your products bears the following claims:

Web site:

- "[C]anthaxanthin -- skin cancer prevention..."
- "The use of canthaxantin may decrease one's chances of getting skin cancer by ... preventing sunburn damage to the skin."
- "Canthaxanthin is a well-studied carotenoid widely distributed throughout nature. ... In animals, carotenoids act as ultra violet light absorbers, ... protecting DNA from genetic damage."
- "[C]anthaxanthin -- ... internal sunscreen"

Product list:

- Under the product heading "Skin Cancer Preventives," Canthaxanthin is listed.
- "Canthaxanthin (internal sunscreen...)"

These claims cause your products to be drugs as defined in sections 201(g)(1)(B) and 201(g)(1)(C) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Even if the labeling for these products did not contain claims which cause them to be drugs, these products are adulterated cosmetics. Your Internet web site promotes these products for coloring the skin. The Act defines the term "cosmetic" at section 201(i)(1) to include articles intended to be introduced into the human body for altering appearance. The following labeling statements establish that these Canthaxanthin products are intended for use to alter the skin color to simulate a suntan:

Web site:

- " [C]anthaxanthin -- ... sunless tanning agent"
- "[W]hen carotenemia occurs [from using canthaxanthin], a much darker orange/red/brown color will appear. On most parts of the body...the coloring is very reminiscent of a tan."
- "[C]anthaxanthin will enhance an actual tan by 2-3 fold."
- "30 mg of canthaxanthin three times daily should be sufficient to saturate the body with the carotenoid. ... [I]t takes about 3-4 weeks AFTER saturation before the color will be golden bronze."
- "[C]antaxanthin – tan promoter..."
- "[G]iving your total body the tan look..."

Product list:

- "Canthaxanthin (...sunless tanning agent)"

The above claims establish that the Canthaxanthin products you are currently marketing on your web site are intended to impart color to the skin, thus making them cosmetic products.

The Act defines the term "color additive" at section 201(t)(1)(B) as a material which, when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color thereto. Canthaxanthin is a color additive. Color additives are deemed to be unsafe unless they are used in accordance with a color additive regulation that specifies the conditions under which the color additive may be

safely used, including the purposes for which it may be used and the product category or categories to which it may be added [section 721(a) of the Act]. There is no color additive regulation currently allowing for the use of canthaxanthin to impart color to the skin or, for that matter, for the use of canthaxanthin in a cosmetic product for any purpose.

Based on the above, the canthaxanthin products you are marketing on your web site are adulterated under section 601(e) of the Act, in that they bear or contain a color additive, namely canthaxanthin, which is unsafe within the meaning of section 721(a) of the Act. It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any cosmetic that is adulterated.

This letter is not intended to be an all inclusive review of your products and labeling . It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Attn: Brenda Baumert, Compliance Officer, at the address on the letterhead.

Sincerely,

Reynaldo R. Rodriguez Jr.
for Michael A. Chappell
District Director

MAC: bcb